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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,999	06/28/1999	ROBERT TERENCE SMITH	S1011/20102	1891

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/19/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/269,999

Applicant(s)

SMITH ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-37 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of request for extension of time (granted), information disclosure statement, and amendment all filed 3-25-02 is acknowledged. Claims 21-37 are pending and claims 20 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-25-02 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

Art Unit: 1615

application was filed, had possession of the claimed invention. The specification does not provide support for the requirement that the porous articles have "predetermined" levels of porosity. The specification shows that porosity level is controlled, but does not provide support that the porosity level is known prior to making the article.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

(a) In order to utilize the system as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors utilizing production of the porous article and manipulation of the onset of polymerization to effect the porous article would have to be resolved by the practitioner for the reasons discussed below.

(b & c) The specification states that the cell/foam structure of the articles is influenced by the length of time before polymerization starts. However, the specification lacks a reasonable level of guidance for how the length of this time affects the foam structure (i.e. "x" number of minutes results in a particular percentage porosity). In other words, the specification does not provide support that a specific amount of time results in a predicted amount of level of porosity.

(d) The nature of development of porous articles is complex.

(e & f) Although the art provides a certain level of guidance regarding to the formation of porous articles, these teachings do not provide sufficient guidance where the specification is lacking. The art demonstrates that uniform porous articles are formed using polymerizable monomer systems, however it does not teach predetermination of the amount of level of porosity.

(g) The claims are broad because there is no guidance for the appropriate period adjustment through addition of initiator and catalyst.

(h) The level of skill of those in the art involving formation of porous articles is high.

The skilled practitioner would first turn to the instant specification for guidance in using the compositions for formation of porous articles, as claimed. However, the specification does not provide sufficient guidance for forming the porous articles, as claimed. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art demonstrates only teaches that uniform porous articles are formed using polymerizable monomer systems and does not specifically teach predetermination of the amount of level of porosity. Finally, said practitioner would turn to trial and error experimentation to make/use porous articles, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1615

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The instant claims require formation of a porous article having a predetermined level of porosity, however, the instant claims do not set forth the parameters for achieving the predetermined level of porosity. In other words, the claim requires a predetermined level of porosity, but then fails to establish the parameters to achieve the level that is predetermined. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 21-29, 31-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sambrook et al (WO 93/04013; hereafter '013).

'013 discloses all the limitations of the instant claims. See the abstract and page 7, line 4 - page 8, line 13 and examples. The pore sizes are disclosed as being dependant on the filter (page 7, last two lines). Filter sizes are then discloses in the examples as being 10-16 microns. Also, Example VIII discloses that the mean pore

Art Unit: 1615

diameter is 24 microns. Controlling the polymerization rate is disclosed at the bottom of page 11).

Response to Arguments

10. Applicant's arguments filed 3-25-02 have been fully considered but they are not persuasive. Applicants argue that '013 does not disclose controlling the period between the formation of the foam and the onset of polymerization and undersintering. '013 discloses drying at 60° C, heating at 400° C and then firing at temperatures as low as 1350° C (Example 9, table after example 10). This is the same process as disclosed in the instant specification. Therefore, '013 meets the limitation where the article is fired at a temperature to undersinter the formed article. In Column 4, lines 3-15 and 52-67, '013 discloses addition of initiator and catalyst for pore formation. The period for onset of polymerization is instantaneous after stirring catalyst into the foam for 30 seconds.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 21- 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013).

'013 teaches all the limitations of the instant claims. '013 does not specify pore sizes greater than 150 microns. '013 does teach adjustment of the pore size through choice of filter, drying under reduced pressure, which causes the foam to expand, or adjusting the speed of stirring when introducing the gas bubbles. Accordingly, adjustment of the pore size would be obvious to one skilled in the art at the time of the invention according to the nature of the intended article (i.e. impregnation of the pores with agents). Firing the solid article at 1350° C is disclosed in '013 and results in a final pore size within the instant range. Thus, firing the solid article at 1250° C does not appear to be critical as the same final pore size appears to be achieved. Controlling the polymerization rate is disclosed at the bottom of page 11).

Response to Arguments

13. Applicant's arguments filed 3-25-02 have been fully considered but they are not persuasive. Applicants argue that '013 does not teach controlling the period between the formation of the foam and the onset of polymerization and undersintering. '013 teaches drying at 60° C, heating at 400° C and then firing at temperatures as low as 1350° C (Example 9, table after example 10). This is the same process as taught in the instant specification. Therefore, '013 meets the limitation where the article is fired at a temperature to undersinter the formed article. In Column 4, lines 3-15 and 52-67, '013 discloses addition of initiator and catalyst for pore formation. The period for onset of polymerization is instantaneous after stirring catalyst into the foam for 30 seconds.

14. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013) in view of Takagi et al (US 4,654,314; hereafter '314) or vice versa.

'013 is relied upon for all that it teaches as stated previously. '013 does not specifically state including the subsequent step of growing bone cells in the porous ceramic product. '013 does state that the products are useful for artificial parts for the body.

'314 is relied upon for teaching that artificial parts comprising growth of bone cells in ceramic products is known. '314 also teaches that the pores of the ceramic product should be between 1 and 600 μm to promote induction of "new-born bone" and turnover of a bone while keeping a good compatibility with a living body.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to incorporate bone cells into the invention of '013 with the motivation of using the ceramic products as artificial parts comprising growth of bone cells and the expectation that the products would be useful for inducing new-born bone, controlling resorption of bone with age, and remedying bone defects.

Also, it would have been obvious to one skilled in the art at the time of the invention to incorporate the invention of '013 into the teachings of '314 as the method of making the ceramic products and the resulting products of '013 may be made more quickly, with better mechanical strength and handling and machining characteristics.

Response to Arguments

Art Unit: 1615

15. Applicant's arguments filed 3-25-02 have been fully considered but they are not persuasive. Applicants reiterate arguments pertaining to '013 alone and appear to further argue that since '314 does not "use the binder alone to form pores leading to the exterior," the instant claims are allowable over the combination of '013 in view of '314 or vice versa. Previous comments pertaining to '013 are again stressed here. Furthermore, the instant claims recite "comprising language" and do not exclude incorporation of elements not recited.

16. Claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013) in combination with Hawley's Condensed Chemical Dictionary (1971) and further in combination with Takagi et al (US 4,654,314; hereafter '314).

'013 and '314 are relied upon for all that they teach as stated previously.

Hawley's Condensed Chemical Dictionary (1971) is relied upon for teaching that the energy required for reduction in particle size of a solid is directly proportional to the increase in surface area (Rittinger's law). In other words, the less energy results in less surface area and bigger particle size which would create larger pores in the same fashion as the space between large marbles in a jar is greater than the space between grains of sand in the same jar.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to decrease the heat (energy) of '013 to achieve larger pore sizes based upon '314, which teaches that the pores of the ceramic product should be between 1 and 600

µm to promote induction of "new-born bone" and turnover of a bone while keeping a good compatibility with a living body and Hawley's which teaches that less energy results in less surface area and bigger particle size which would create larger pores.

Response to Arguments

17. Applicant's arguments filed 3-25-02 have been fully considered but they are not persuasive. Applicant's comments pertaining to the combination of '013 in view of '314 or vice versa are relied upon to overcome the rejection of claims 21-36 under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013) in combination with Hawley's Condensed Chemical Dictionary (1971) and further in combination with Takagi et al (US 4,654,314; hereafter '314). Therefore, the previous comments regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013) in view of Takagi et al (US 4,654,314; hereafter '314) or vice versa are relied upon.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

Application/Control Number: 09/269,999


Page 11

Art Unit: 1615

308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
June 10, 2002


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